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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,637	02/12/2004	Osamu Kato	049400-5027	1776
9629 7590 01/24/2008 MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			EXAMINER HALL, DEANNA K	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 01/24/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/776,637

Applicant(s)

KATO ET AL.

Examiner

Deanna K. Hall

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date See Continuation Sheet.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :August 27, 2007; August 31, 2007.

## **DETAILED ACTION**

### ***Acknowledgments***

1. This office action is in response to the reply filed on November 1, 2007.
2. In the reply, the applicant cancelled claims 1-9 and added new claims 10-12.

### ***Information Disclosure Statement***

3. The information disclosure statements (IDS) submitted on August 31, 2007 and August 27, 2007 are in compliance with the provisions of 37 CFR 1.97(b). Accordingly, the IDSs are being considered by the Examiner.

### ***Drawings***

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the three-layered catheter device used with the flexible hollow tube body as recited in claim 10 or claim 11 (claim 12) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.
5. Further, the helical grooves as claimed in claim 10 are not shown in the drawings.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

6. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "a three-layered catheter device" is not defined explicitly in the specification or implicitly through its usage. Thus, the term renders the claim indefinite since one of ordinary skill in the art would not be able to ascertain the scope of the claim. It is unclear in claim 12 whether or not the three-layered catheter device is the same as the three-layered flexible hollow tube body. Also, it is unclear if the knife-edge circle front is just on the lower-layer tube or if it is on the upper-layer tube, the outer-layer tube and the lower-layer tube. Furthermore, the Examiner has

interpreted the claim in a manner that would render the prior art applicable. *Ex parte Ionescu*, 222 USPQ 537 (Bd. App. 1984).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. **Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson (US 4,516,972) in view of Houk (US 3,028,720) further in view of Shiber (US 5,653,696).**

Samson discloses a catheter device comprising: a flexible hollow tube body 11 formed by a plurality of austenitic stainless steel wires cylindrically stranded around an elongate core 12 into a wire-rope configuration C2 L24-29. It is the examiner's position that the ribbon 16 of flexible material as disclosed in Samson is capable of being austenitic stainless steel. One end of the wires are secured to a rotational chuck of a twisting device and the other end of the wires are secured to a slidable chuck 32, 33, Fig. 3. While Samson discloses the invention as substantially claimed, Samson does not directly disclose the second chuck having a weight depending from it which causes the twisting of the wire. Houk, in the analogous art, teaches a rotating chuck 18 and a slidable chuck 16 from which a weight 22 is depended and causes the twisting, C2 L1-16, Fig. 1. Therefore, it would have been obvious to a person having ordinary skill in

the art at the time the invention was made to have modified the device of Samson with the slidable chuck and weight as taught by Houk for twisting the steel wires into a rope configuration. Further, it is examiner's position that with the use of austenitic stainless steel wires it is well known in the art for electric currents to be drawn on the wires to set the shape of the rope in the austenitic phase.

Samson further discloses the flexible hollow tube having a plurality of zones comprising a rigid-flexible gradient structure Fig. 1, C2 L62- C3 L2. It is inherent that some sort of clamp must be used in Samson to obtain variations in torsional rigidity by changing the pitch or density of the helical winding of the ribbon.

Samson and Houk, as described above refer to the process of making the flexible hollow tube body. Herein described, Shiber, refers to the structural components of the flexible hollow tube body.

The combination of Samson and Houk discloses the invention as substantially claimed (see above). However, this combination does not directly disclose a knife-edge circle front welded to a leading end of the flexible hollow tube body as a blade edge which diametrically decreases progressively as approaching forward; and helical grooves provided inside the flexible tube body to carry away the hard clot powder. Shiber, in the analogous art, teaches a flexible tube with a knife-edge circle front 22, 102, Figs. 24-26 and an outwardly arcuated blade edge which diametrically decreases progressively as approaching outward, Fig. 6. Shiber further teaches helical grooves 25 inside the flexible tube body to remove the clot powder material. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention

was made to have modified the combination of Samson/Houk with the helical grooves and knife-edge circle front as taught by Shiber for breaking up and removing clot material.

**9. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Samson (US 4,516,972) in view of Houk (US 3,028,720) in view of Shiber (US 5,653,696) further in view of Toro et al. (US 6,342,066) ("Toro").**

The combination of Samson/Houk/Shiber discloses the invention as substantially claimed (see above). However, this combination does not directly disclose a three-layered structure with an upper-layer slidably fit into a lower-layer tube and an outer-layer tube fit into the upper-layer tube and a self-expansible stent provided on the lower-layer tube and pushed by the outer-layer tube to set the stent. Toro, in the analogous art, teaches a upper-layer tube 20, a lower-layer tube 40, an outer-layer tube 26 and a stent 18 mounted on the lower-layered tube 40 and released by means of the outer tube 26. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the combination of Samson/Houk/Shiber with the three-layered catheter device with stent as taught by Toro for releasing a stent into a desired location of the targeted vessel.

### ***Response to Arguments***

10. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.



***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deanna K. Hall whose telephone number is 571-272-2819. The examiner can normally be reached on M-F 9:00am-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Deanna K. Hall  
Examiner  
AU 3767

dkh

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER  
*Kevin C. Sirmons*